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PATENT SPECIFICATION

DRAWINGS ATTACHED

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COMPLETE SPECIFICATION

Cardiac Apparatus

We, ELECTRO-CATHETER CORPORATION, of 932 East Elizabeth Avenue, Linden, State of New Jersey, United States of America, a corporation organised and existing under the laws of the State of New Jersey, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement: —

This invention relates to cardiac apparatus constructed and arranged to effectively artificially stimulate the heart.

Cardiac arrest is a situation in which the heart has simply stopped beating, and the person is ostensibly dead. Reasons for the heart ceasing to function are many, for example, accident, electrocution, poisoning, and shock. Cardiac apparatus is presently available for artificially stimulating the stopped heart and thus resuscitating a person or individual. Similarly, prescribed procedures for artificially stimulating the heart in an instance of cardiac arrest are also presently known. As is considered readily apparent, time is a critical factor. Thus, the user must be able to effect the necessary procedure with extreme facility, with the expenditure of a minimal amount of effort, all in the least possible time. It has been found that presently available cardiac apparatus is not capable of entirely satisfying these criteria.

According to one aspect of the present invention, there is provided cardiac apparatus for artificially stimulating a heart and comprising, in combination: an inner electrically conductive element having a tip and a distal end and an outer electrically conductive element surrounding the inner element and spaced therefrom by an electrically insulating element terminating at a region remote from the tip, beyond which region said inner element and an auxiliary outer element insulated from said outer element are disposed in an electrically conductive relationship.

According to another aspect of the present invention, there is provided cardiac apparatus for artificially stimulating a heart and comprising, in combination: an inner electrode fabricated of an electrically conductive flexible material having a tip of hook-shaped configuration and a distal end; an outer electrode comprising a coil spring fabricated of an electrically conductive flexible and resilient material; said inner electrode being of greater length than said outer electrode, and said outer electrode terminating at a region remote from said tip; a joint fabricated of a dielectric material affixing said inner and outer electrodes together at said tip; an insulating tube fabricated of dielectric material positioned between said inner and outer electrodes, and extending from said tip to said region; an auxiliary outer electrode comprising a coil spring positioned about said inner electrode, and extending from said region to said distal end; a joint fabricated of a dielectric material positioned at said region and joining said inner, outer and auxiliary outer electrodes; a sleeve positioned about said outer and auxiliary outer electrodes for protecting the joint at said region by precluding excessive flexing at that location; a plurality of spaced markers located upon said outer electrode; and an impulse generator for connection to said outer and said auxiliary outer electrodes.

The invention will now be described with reference to the accompanying drawings, in which: —

Figure 1 is an elevational view, partially in section and drawn to an enlarged scale, of one embodiment of cardiac apparatus constructed in accordance with the principles of the present invention;

Figure 2 is a cross-sectional view taken

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along the line 2—2 of Figure 1;

Figure 3 is a cross-sectional view taken along the line 3—3 of Figure 1;

Figure 4 is an elevational view, partially in section and drawn to an enlarged scale, of another embodiment of cardiac apparatus constructed in accordance with the principles of the present invention;

Figure 5 shows a needle for facilitating the insertion of the apparatus of Figure 4 through the chest wall to the heart according to the first step in the use of the cardiac apparatus;

Figure 6 is a view similar to Figure 5, illustrating the second step in the use of the cardiac apparatus;

Figure 7 is a view similar to Figures 5 and 6, illustrating the third step in the use of the cardiac apparatus;

Figure 8 is a view similar to Figures 5 to 7, illustrating the next step in the use of the cardiac apparatus; and

Figure 9 is a view similar to Figures 5 to 8, illustrating the final step in the use of the cardiac apparatus.

With reference now to Figure 1, there is illustrated therein one embodiment of cardiac apparatus constructed in accordance with the principles of the present invention, and generally designated by the reference character 10.

The cardiac apparatus 10 comprises a first, inner electrode 12 that terminates at one end or at the tip thereof in a hook or loop 14. The inner electrode 12 is fabricated of any suitable electrically conductive material. The cardiac apparatus 10 further comprises a second, outer or peripheral electrode 16. This electrode also is fabricated of a suitable electrically conductive material, and preferably takes the form of an extremely flexible and resilient coil spring, the coils of which are positioned close to or immediately adjacent one to another.

The inner and outer electrodes 12 and 16, respectively, are fixed or joined to one another at a joint 18 to preclude relative movement therebetween. The joint 18 is fabricated of any suitable dielectrical or non-conductive material, as, for example, an epoxy resin.

The inner electrode 12 is of greater length than the outer electrode 16, the latter terminating at a location or region 20 remote from the tip 14. An insulating tube 22 that is fabricated of a suitable dielectric material is positioned between the electrode 12 and 16, and extends from the tip 14 to the location or region 20. As is considered readily apparent, the insulating tube 22 precludes shorting of the electrode between the tip 14 and the region 20 at any location therebetween. This is important since, as will hereinafter more fully be described, the myocardium and the outer electrode 16 define one path of an electrical circuit.

The cardiac apparatus 10 further comprises an auxiliary outer electrode 24 that extends substantially from the location or region 20 to a distal end 26, at which the inner electrode 12 also terminates. The electrode 24 is of similar material and construction to electrode 16. The outer electrode 16 and the auxiliary outer electrode 24 are affixed or secured to one another at the location or region 20 by a joint 28 that is fabricated of any suitable dielectric or non-conductive material, such as an epoxy resin. Accordingly, relative movement between the inner electrode 12 and the outer electrode 16 is precluded at the region 20, as it is at the tip 14. Relative movement is also precluded between the inner electrode 12 and the auxiliary outer electrode 24, and also between the latter and the outer electrode 16.

The cardiac apparatus 10 further comprises a tubular movable sleeve 30 that is fabricated of any suitable material, such as plastics, the sleeve 30 is particularly adapted to be disposed at the location or region 20 and about the joint 28 to preclude excessive flexing of the device 10 at this location, and possibly damage thereto. To properly locate the sleeve 30, it is recessed interiorly thereof to define a shoulder 32 that is particularly adapted to be disposed in abutting engagement with the joint 28. To facilitate movement of the sleeve 30 longitudinally or axially of the cardiac apparatus, the sleeve comprises an annular collar 34 extending completely peripherally thereabout.

Still further, the cardiac apparatus 10 comprises a first or primary marker 38 and a secondary or auxiliary marker 40, for a purpose that will hereinafter more fully be described. The markers 38 and 40 may be fabricated of any suitable material, and are affixed to the outer electrode 16 in any suitable manner.

With particular reference now to Figures 4 to 9, wherein like reference characters to Figures 1 to 3 indicate like parts, but wherein the like reference characters are primed, there is illustrated therein another embodiment of cardiac apparatus constructed in accordance with the principles of the present invention, and generally designated by the reference character 10'.

The cardiac apparatus 10' is substantially the same as the device illustrated in Figures 1 to 3, with the exception that the tubular sleeve 30' is affixed or secured to the other electrode 16' and the auxiliary outer electrode 24' at the location or region 20'. The sleeve 30', again, may be fabricated of any suitable material, and is affixed or secured to the outer electrodes 16' and 24' in any suitable manner. Since the sleeve is affixed thereto at the location 20', once again excessive flexing at this location is precluded, as is possible damage at this location to the

joint 28'. Since the sleeve 30' is affixed or secured to the electrodes 16' and 24', it is of less diametral dimensional extent than the sleeve 30, for reasons that will hereinafter more fully be understood.

In the cardiac apparatus of the present invention, the insulating tube, namely, the tube 22 of the device 10, and the tube 22' of the device 10', extends from the tip 14 or 14' to the location or region 20 or 20', respectively. The tube terminates at the location or region, so that no insulation is present between the inner electrode 12 or 12' and the surrounding auxiliary outer electrode 24 or 24' respectively. Accordingly, although the inner electrode 12 or 12' and the outer electrode 24 or 24' are effectively spaced one from the other they are in electrical communication with one another. Accordingly, current supplied to the auxiliary outer electrode will be transmitted to the inner electrode, and then to the tip of the cardiac device. There is thus defined one path of an electrical circuit. Another path of the electrical circuit will at least comprise the outer electrode 16 or 16'. The presence of the insulating tube 22 or 22' will preclude shorting between the two paths of the electrical circuit at any location between the tip 14 or 14' and the region 20 or 20', respectively. It can be said, therefore, that there is defined a bi-polar cardiac apparatus in that the apparatus in and of itself comprises an electrical circuit. The apparatus presents an extreme degree of flexibility and resiliency. This is particularly true since the outer electrode and the auxiliary outer electrode are fabricated of coil springs. As a result, cardiac apparatus constructed in accordance with the present invention will be easy to handle, will provide for freedom of movement of the heart while maintaining electrical contact therewith, and will substantially reduce, if not completely eliminate, the possibility of damage to the tissue and muscle of the heart and body with which the cardiac apparatus is in contact. At the same time, there is presented a cardiac apparatus that is economical of manufacture, while yet being reliable, sturdy and durable in use, even over long periods of time, and repeated utilizations.

With particular reference now to Figures 5 to 9, there are illustrated therein the various steps of the procedure for utilizing the cardiac apparatus or device 10' illustrated in Figure 4.

When an instance of cardiac arrest is diagnosed, a needle 42 of any suitable and conventional construction, approximately 6 inches in length, is inserted through the chest wall 44 substantially at the fourth and fifth intercostal (occurring between the ribs of the torso) space. The needle 42 is then inserted into the ventricular wall 46 until it reaches a location at which it just enters the ventricule or chamber cavity 48. This may be the left ventricule of the heart. Entry to the right ventricule can be made by passing the needle under the sternum, or substernally.

The needle 42 may be of any suitable and conventional construction, as hereinbefore pointed out, and will comprise a needle portion 50 and a sleeve portion 52. The needle portion 50 is now removed, as illustrated in phantom in Figure 5, and the cardiac apparatus 10' inserted into the sleeve portion 52. The cardiac apparatus is caused to move into the sleeve portion until the primary marker 38' is adjacent to the hub of the sleeve portion. When the primary marker is disposed at this location, the tip 14' will just have emerged from the sleeve portion 52, and, therefore, will have just entered the ventricular wall 46. This is true since the distance between the tip 14' and the primary marker 38' is chosen to be substantially the same as the distance between the tip and the hub of the sleeve portion 52. Accordingly, the user can follow the progress of the cardiac apparatus through the sleeve portion, and maintain a check on the tip 14'. In particular, the user can determine when the tip just emerges from the needle portion at the ventricular wall 46.

The distance between the primary and secondary markers 38' and 40', respectively, is generally arbitrarily chosen. However, the distance between these markers is chosen to dispose the tip 14' of the apparatus 10' a sufficient distance into the ventricular cavity 48 when the auxiliary marker 40' is positioned adjacent to the hub of the sleeve portion 52. It can also be said that movement of the apparatus 10' continues until contact with the endocardium (not shown) in the ventricular cavity is felt.

The cardiac apparatus 10' is now grasped or held at a location remote from the chest wall 44, enabling the sleeve portion 52 to be completely withdrawn therefrom. The cardiac apparatus 10' is then grasped near the surface of the chest wall 44, enabling the sleeve portion 52 to be slipped off of the apparatus or device. This can be accomplished with facility since the diameter of the sleeve 30' is slightly less than the interior diameter of the sleeve portion 52.

An impulse generator 54 is now connected to the cardiac apparatus or device 10' across the sleeve 30'. The impulse generator 54 may be of any suitable and conventional construction capable of delivering an electric current approximating in strength, frequency and distribution the normal current of the heart. The cardiac apparatus or device 10', as hereinbefore pointed out, is bi-polar in that it defines a complete electric circuit, with the exception of a source of energy, in and of itself. Accordingly, connecting the impulse generator 54 to the auxiliary outer electrode 24' by a lead

56 will transmit current to the inner electrode 12', since no dielectric material is disposed therebetween. The impulses generated by the generator 54 will thus be transmitted to the tip 14', and thence to the tissue of the heart. The heart tissues are electrically conductive, so that the impulses received thereby will be transmitted to the outer electrode 16', and thence returned to the impulse generator 54 by a lead 58.

The procedure for utilizing the cardiac apparatus 10 of Figure 1 is substantially the same as that just described, with the exception that the sleeve 30 must first be removed before removing the sleeve portion 52 of the needle 42. Subsequent to its removal, the sleeve 30 is again positioned upon the cardiac apparatus, and moved to a position at which the shoulder 32 abuts the joint 28, for the reasons and purposes hereinbefore described.

By constructing and arranging the inner electrode 12' of an electrically conductive material that is at least flexible, and by constructing and arranging the outer electrode 16' and 24' of a coil spring, which is resilient as well as flexible, there is provided an extremely flexible and resilient cardiac apparatus for artificially stimulating a heart that has ceased beating in an unusually efficient manner, with extreme facility, and with the expenditure of a minimal amount of time. This flexibility and resiliency is also important in that it enables the cardiac apparatus to follow the motion of the heart, while at the same time substantially reducing, if not completely eliminating, damage and irritation to the tissue of the body. Accordingly, cardiac apparatus of the present invention can be utilized to stimulate the heart for substantial periods of time, and for such periods of time can be retained in the body without causing discomfort thereto. Moreover, cardiac apparatus of the present invention is bi-polar in that it, in and of itself, defines two contacts across which a potential difference may be established for enabling electric impulses to be transmitted through the circuit defined thereby. This is accomplished by constructing and arranging the outer electrode of separate coil springs that are insulated from one another, and insulating one of the outer electrodes from an inner electrode.

In Figure 1, the tip area and the region 20 of the cardiac apparatus 10 has been drawn to an enlarged scale to facilitate an understanding of the present invention, and, in effect, has been shown as it would appear through a magnifying glass. That element has not been described, however, since it does not comprise a part of the present invention.

WHAT WE CLAIM IS:—

1. Cardiac apparatus for artificially stimulating a heart and comprising, in combination: an inner electrically conductive element having a tip and a distal end and an outer electrically conductive element surrounding the inner element and spaced therefrom by an electrically insulating element terminating at a region remote from the tip, beyond which region said inner element and an auxiliary outer element insulated from said outer element are disposed in an electrically conductive relationship.

2. Cardiac apparatus as claimed in Claim 1, wherein said inner element comprises an electrode fabricated of a flexible material and wherein said outer elements consist of two coil springs fabricated of flexible and resilient material.

3. Cardiac apparatus as claimed in Claim 2, wherein the coil spring beyond said region defines the auxiliary outer element which is separated from the main outer element but is affixed thereto at said region by a joint fabricated dielectric material.

4. Cardiac apparatus as claimed in Claim 3, wherein a sleeve is positioned about said main and auxiliary outer elements for protecting the joint at said region by precluding excessive flexing at that location.

5. Cardiac apparatus as claimed in Claim 3 or Claim 4, wherein a plurality of spaced markers are located upon said main outer element.

6. Cardiac apparatus as claimed in any one of Claims 3 to 5 wherein an impulse generator is adapted to be connected to said main outer and to said auxiliary outer elements across the joint at said region.

7. Cardiac apparatus as claimed in any one of Claims 4 to 6, wherein said sleeve is movable longitudinally of said main outer and auxiliary outer elements for removal therefrom and comprises an interior recess that defines a shoulder adapted to abut against the joint at said region for precluding movement of the sleeve beyond that location.

8. Cardiac apparatus as claimed in Claim 6, wherein said sleeve is affixed to said main outer and auxiliary outer elements at said region.

9. Cardiac apparatus for artificially stimulating a heart and comprising, in combination: an inner electrode fabricated of an electrically conductive flexible material having a tip of hook-shaped configuration and a distal end; an outer electrode comprising a coil spring fabricated of an electrically conductive flexible and resilient material; said inner electrode being of greater length than said outer electrode, and said outer electrode terminating at a region remote from said tip; a joint fabricated of a dielectric material affixing said inner and outer electrodes together at said tip; an insulating tube fabricated of dielectric material positioned between said inner and outer electrodes, and extending from said tip to said region; an auxiliary outer electrode comprising a coil spring positioned

about said inner electrode, and extending from said region to said distal end; a joint fabricated of a dielectric material positioned at said region and joining said inner, outer and auxiliary outer electrodes; a sleeve positioned about said outer and auxiliary outer electrodes for protecting the joint at said region by precluding excessive flexing at that location; a plurality of spaced markers located upon said outer electrode; and an impulse generator for connection to said outer and said auxiliary outer electrodes.

10. Cardiac apparatus as claimed in any one of the preceding claims, and comprising a needle having a sleeve portion and a needle portion.

11. Cardiac apparatus for artificially stimulating a heart substantially as hereinbefore described with reference to Figures 1 to 3 or Figure 4 of the accompanying drawings.

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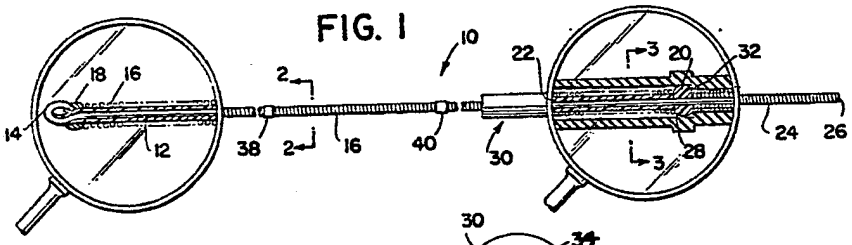
1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

FIG. 1



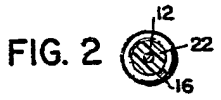


FIG. 2

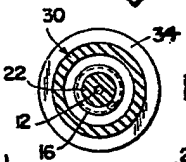


FIG. 3

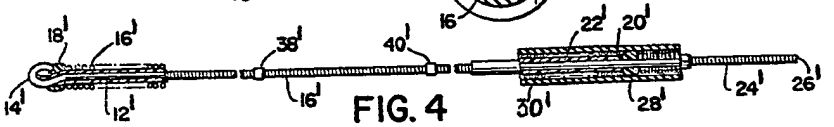


FIG. 4

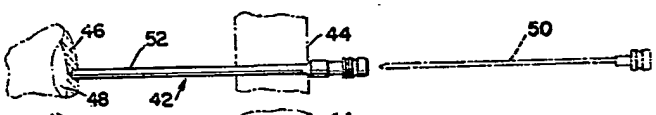


FIG. 5

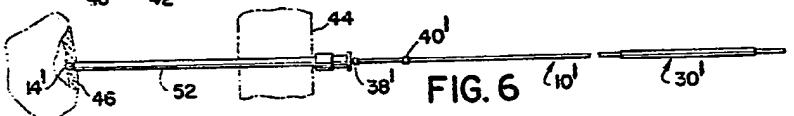


FIG. 6

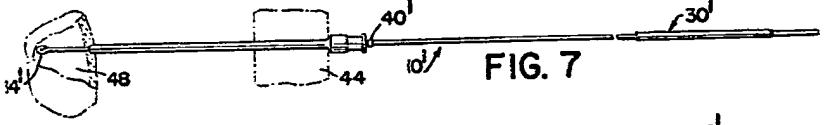


FIG. 7

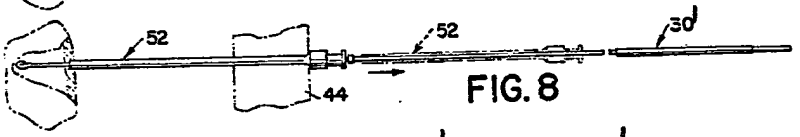


FIG. 8

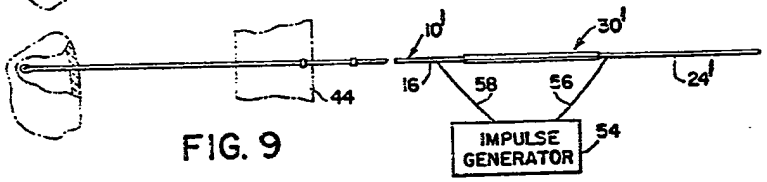


FIG. 9